Amendments to the Claims

This listing of the claims will replace all prior versions and listings of the claims.

Listing of Claims:

1. (currently amended) A pharmaceutical composition, comprising:

(a) a polypeptide comprising Ser (69) – Ser (208) of SEQ ID NO:2 in a concentration range of about 0.02 to about 40 mg/ml (w/v);

(b) a buffer having a buffering capacity of between about 5.0 and about 8.0 at a concentration range of about 5 mM to about 50 mM;

(c) a pharmaceutically acceptable diluent to bring the composition to a designated volume; and

(d) a preservative consisting of ~~selected from the group consisting of m-cresol, chlorobutanol, and~~ a mixture of methyl paraben and propyl paraben, wherein said methyl paraben is at a concentration of 0.1% to 0.2% and said propyl paraben is at a concentration of 0.01% to 0.05%,

wherein said polypeptide has KGF-2 activity.

2. (original) The pharmaceutical composition of claim 1, further comprising:

(a) a chelating agent at a concentration range of about 1 mM to about 10 mM; and

(b) a tonicifier at a concentration range of about 0 mM to about 150 mM.

3. (original) The pharmaceutical composition of claim 2, wherein said tonicifier is selected from the group consisting of NaCl, glycine, sucrose, mannitol, and mixtures thereof.

4. (original) The pharmaceutical composition of claim 1, further comprising one of:

(a) about 0.5% to about 2% w/v glycerol,

(b) about 0.1% to about 1% w/v methionine, or

(c) about 0.1% to about 2% w/v monothioglycerol.

5. (previously presented) The pharmaceutical composition of claim 1, wherein said polypeptide is present in a concentration range of about 0.05 to about 30 mg/ml (w/v).

6. (previously presented) The pharmaceutical composition of claim 5, wherein said polypeptide is present in a concentration range of about 0.1 to about 20 mg/ml (w/v).

7. (previously presented) The pharmaceutical composition of claim 6, wherein said polypeptide is present in a concentration range of about 0.2 to 4 mg/ml.

8. (canceled)

9. (original) The pharmaceutical composition of claim 1, wherein said diluent is water.

10. (original) The pharmaceutical composition of claim 2, wherein said chelating agent is EDTA at a concentration of about 1 mM, and said tonicifier is present at a concentration of about 125 mM.

11. (original) The pharmaceutical composition of claim 1, wherein said pH is from about pH 5.5 to about pH 6.5.

12. (original) The pharmaceutical composition of claim 11, wherein said pH is about pH 6.2.

13. (original) The pharmaceutical composition of claim 1, wherein said buffer is selected from the group consisting of phosphonic, acetic, aconitic, citric, glutaric, malic, succinic carbonic acid, and an alkali or alkaline earth salt thereof.

14. (original) The pharmaceutical composition of claim 13, wherein said buffer is a phosphate, acetate or citrate salt.

15. (original) The pharmaceutical composition of claim 13, wherein said buffer is a citrate salt.

16. (original) The pharmaceutical composition of claim 1, wherein said buffer is present in a concentration range of about 5 mM to about 30 mM.

17. (original) The pharmaceutical composition of claim 16, wherein said buffer is a citrate salt present in a concentration of from about 10 mM to about 20 mM.

18. (original) The pharmaceutical composition of claim 1, further comprising a stabilizing amount of one or more of (a) an antioxidant or (b) a thiol-compound.

19. (original) The pharmaceutical composition of claim 1, wherein said composition is maintained at a temperature at or below -20°C.

20. (previously presented) The pharmaceutical composition of claim 1, wherein said polypeptide is selected from the group consisting of (i) Ser (69) – Ser (208) of SEQ ID NO:2; (ii) Ser (69) – Ser (208) of SEQ ID NO:2 with a methionine at the N-terminus; and (iii) a mixture of (i) and (ii).

21. (original) The pharmaceutical composition of claim 1, further comprising a bulking agent.

22. (original) The pharmaceutical composition of claim 21, wherein said bulking agent is selected from the group consisting of sucrose, glycine, mannitol, trehalose, and mixtures thereof.

23. (original) The pharmaceutical composition of claim 22, wherein said bulking agent is sucrose or a mixture of sucrose and glycine.

24. (original) The pharmaceutical composition of claim 2, further comprising a bulking agent.

25. (original) The pharmaceutical composition of claim 22, wherein said bulking agent is present in a concentration of about 2% to about 10% w/v.

26. (original) The pharmaceutical composition of claim 22, wherein said bulking agent is 5% mannitol, 7% sucrose, 8% trehalose, or 2% glycine + 0.5% sucrose.

27. (original) The pharmaceutical composition of claim 21, wherein said pH is about pH 6.2.

28. (original) The pharmaceutical composition of claim 21, wherein said diluent is water.

29. (original) The pharmaceutical composition of claim 21, wherein said buffer is selected from the group consisting of phosphonic, acetic, aconitic, citric, glutaric, malic, succinic carbonic acid, and an alkali or alkaline earth salt thereof.

30. (original) The pharmaceutical composition of claim 29, wherein said buffer is a phosphate or citrate salt.

31. (original) The pharmaceutical composition of claim 30, wherein said buffer is a citrate salt.

32. (original) The pharmaceutical composition of claim 28, wherein over 90% of the water is removed by lyophilization.

33. (original) The pharmaceutical composition of claim 32, which is reconstituted in with an amount of sterile water effective to maintain isotonic conditions of 290 mOsm.

34-35. (canceled)

36. (original) The pharmaceutical composition of claim 21, wherein said buffer is added in a concentration from about 5 mM to about 50 mM

37. (original) The pharmaceutical composition of claim 36, wherein said buffer is citrate at a concentration of about 10 mM.

38. (original) The pharmaceutical composition of claim 21, further including a stabilizing amount of one or more of (a) an antioxidant, or (b) a thiol-compound.

39. (original) The pharmaceutical composition of claim 32, wherein said composition is reconstituted in sterile water containing a stabilizing amount of an antioxidant comprising: a) about 0.01% to about 2% w/v monothioglycerol, b) about 0.01% to about 2% w/v ascorbic acid, c) about 0.01% to about 2% w/v methionine or d) combinations thereof.

40. (original) The pharmaceutical composition of claim 1, further comprising a thickening agent in an amount effective to raise the viscosity to about 50 to about 10,000 cps.

41. (original) The pharmaceutical composition of claim 40, wherein said thickening agent is present in an amount effective to raise the viscosity to about 50 to about 1,000 cps.

42. (original) The pharmaceutical composition of claim 41, wherein said thickening agent in an amount effective to raise the viscosity to about 200 to about 300 cps.

43. (previously presented) The pharmaceutical composition of claim 1, further comprising a thickening agent present in a concentration of 0 to 5% (w/w).

44. (previously presented) The pharmaceutical composition of claim 40, wherein said thickening agent is a water soluble etherified cellulose or a carbomer.

45. (original) The pharmaceutical composition of claim 44, wherein said etherified cellulose is an alkyl cellulose, hydroxyalkyl cellulose, carboxyalkyl cellulose or alkylhydroxyalkyl cellulose.

46. (previously presented) The pharmaceutical composition of claim 44, wherein said etherified cellulose is methylcellulose, hydroxyethyl cellulose, hydroxy propyl cellulose, hydroxy propyl methylcellulose, or carboxymethyl cellulose.

47. (previously presented) The pharmaceutical composition of claim 1, further comprising a thickening agent, wherein said thickening agent is a water soluble etherified cellulose derivative selected from the group consisting of methyl cellulose, hydroethyl cellulose, hydroxy propyl cellulose, hydroxy propyl methylcellulose, or carboxymethyl cellulose, wherein said etherified cellulose derivative has a molecular weight of about 50,000 to about 700,000 and is present in a concentration of about 0 to about 20% by weight.

48. (original) The pharmaceutical composition of claim 47, wherein said etherified cellulose derivative has a molecular weight of about 80,000 to about 240,000 and is present in a concentration of about 2% to about 8% by weight.

49. (original) The pharmaceutical composition of claim 42, wherein said buffer is citrate in a concentration of about 10 mM to about 50 mM.

50. (original) The pharmaceutical composition of claim 49, wherein said buffer is citrate in a concentration of about 10 mM to about 20 mM citrate.

51. (original) The pharmaceutical composition of claim 49, wherein said bulking agent is sucrose in a concentration of about 0% to about 5% sucrose.

52. (original) The pharmaceutical composition of claim 51, wherein said thickening agent is added directly to a liquid formulation and thereafter lyophilized.

53. (original) The pharmaceutical composition of claim 51, wherein said thickening agent is added to a lyophilized formulation by reconstituting said formulation by adding a suitable diluent having a thickening agent dissolved therein.

54. (currently amended) The pharmaceutical composition of claim 21, further comprising a thickening agent in an amount effective to raise the viscosity ~~vicosity~~ to about 50 to about 10,000 cps.

55. (original) The composition of claim 1, further comprising a gelling agent in an amount effective to raise the viscosity to about 0 to about 10,000 cps at room temperature.

56. (original) The composition of claim 21, further comprising a gelling agent in an amount effective to raise the viscosity to about 0 to about 10,000 cps at room temperature.

57. (original) The composition of claim 55, wherein said gel forming agent is a water-soluble polymer capable of forming a viscous aqueous solution, or non-water soluble, water-swellable polymer capable of forming a viscous solution.

58. (original) The composition of claim 57, wherein said gel forming agent is a high molecular weight polymer selected from the group consisting of vinyl polymer, polyoxyethylene-polyoxypropylene copolymer, polysaccharide, protein, poly(ethylene oxide), acrylamide polymer or a salt thereof.

59. (previously presented) The composition of claim 58, wherein said gel forming agent is (1) a vinyl polymer selected from the group consisting of polyacrylic acid, polymethacrylic acid, polyvinyl pyrrolidone polyvinyl alcohol, and salts and esters thereof; or (2) a polysaccharide selected from the group consisting of a cellulose derivative, a glycosaminoglycan, agar, pectin, alginic acid, dextran, α-amylose, amylopectin, chitosan, or salts esters thereof.

60. (original) The composition of claim 58, wherein said gel forming agent is a glycosaminoglycan selected from the group consisting of hyaluronic acid, chondroitin, chondroitin-4-sulfate, heparan sulfate, heparin and salts and esters thereof.

61. (original) The composition of claim 60, wherein said glycosaminoglycan is present in combination with collagen, gelatin, or fibronectin.

62. (original) The composition of claim 58, wherein said gel forming agent is an acrylamide polymer selected from the group consisting of a polyacrylamide or a polymethacrylamide.

63. (original) The composition of claim 58, wherein said gel forming agent is a polyoxyethylene-polyoxypropylene block copolymer.

64. (original) The composition of claim 63, which comprises about 10 to about 60% by weight of a polyoxyethylene-polyoxypropylene block copolymer having an average molecular weight of about 500 to 50,000.

65. (original) The composition of claim 64, which comprises about 14 to about 18% by weight of a polyoxyethylene-polyoxypropylene block copolymer having a molecular weight in the range 1,000 to 15,000.

66. (previously presented) The pharmaceutical composition of claim 1, wherein said polypeptide is present in a concentration range of about 0.1 mg/ml to about 10 mg/ml (w/v).

67-70. (canceled)

71. (original) The pharmaceutical composition of claim 1, further comprising one of:

(a) lysine;

(b) hydroxypropyl-β-cyclodextrin; and

(c) sulfated-β-cyclodextrin;

or combinations thereof.

72. (canceled)

73. (currently amended) The pharmaceutical composition of claim ~~72~~ 1, wherein said mixture consists of 0.18% methyl paraben and 0.02% propyl paraben.

74. (previously presented) A pharmaceutical composition comprising:

(a) about 1.0 mg/ml of a polypeptide comprising Ser (69) – Ser (208) of SEQ ID NO:2;

(b) 20 mM citrate, pH 5-5.5; and

(c) 0.01% polysorbate 80.

75. (original) The pharmaceutical composition of claim 74, further comprising 1 mM EDTA.

76. (previously presented) A pharmaceutical composition comprising:

(a) about 3.3 mg/ml of a polypeptide comprising Ser (69) – Ser (208) of SEQ ID NO:2;

(b) 10 mM sodium citrate;

(c) 20 mM sodium chloride;

(d) 1 mM EDTA;

(e) 2% w/v glycine;

(f) 0.5% w/v sucrose; and

(g) water;

wherein the composition is at a pH or about 6.2.

77. (previously presented) The pharmaceutical composition of claim 76, wherein over 90% of the water is removed by lyophilization.

78. (previously presented) A pharmaceutical composition comprising:

(a) about 1.0 mg/ml of a polypeptide comprising Ser (69) – Ser (208) of SEQ ID NO:2;

(b) 0.46% hydroxyethylcellulose;

(c) 7% sucrose;

(d) 20 mM sodium citrate;

(e) 20 mM sodium chloride;

(f) 1 mM EDTA;

wherein the composition is at a pH of about 6.2.

79. (previously presented) The pharmaceutical composition of claim 74, wherein said polypeptide is selected from the group consisting of: (i) Ser (69) – Ser (208) of SEQ ID NO:2; (ii) Ser (69) – Ser (208) of SEQ ID NO:2 with a methionine at the N-terminus; and (iii) a mixture of (i) and (ii).

80. (previously presented) The pharmaceutical composition of claim 76, wherein said polypeptide is selected from the group consisting of: (i) Ser (69) – Ser (208) of SEQ ID NO:2; (ii) Ser (69) – Ser (208) of SEQ ID NO:2 with a methionine at the N-terminus; and (iii) a mixture of (i) and (ii).

81. (previously presented) The pharmaceutical composition of claim 78, wherein said polypeptide is selected from the group consisting of: (i) Ser (69) – Ser (208) of SEQ ID NO:2; (ii) Ser (69) – Ser (208) of SEQ ID NO:2 with a methionine at the N-terminus; and (iii) a mixture of (i) and (ii).

82. (currently amended) A pharmaceutical composition produced by the process of admixing:

(a) a polypeptide comprising Ser (69) – Ser (208) of SEQ ID NO:2 in a concentration range of about 0.02 to about 40 mg/ml (w/v);

(b) a buffer having a buffering capacity of about pH 5.0 to about pH 8.0 at a concentration range of about 5 mM to about 50 mM;

(c) a pharmaceutically acceptable diluent to bring the concentration to a designated volume; and

(d) a preservative consisting of ~~selected from the group consisting of m-cresol, chlorobutanol, and~~ a mixture of methyl paraben and propyl paraben, wherein said methyl paraben is at a concentration of 0.1% to 0.2% and said propyl paraben is at a concentration of 0.01% to 0.05%,

wherein said polypeptide has KGF-2 activity.

83. (currently amended) The pharmaceutical composition of claim 82, further comprising one or more of:

(a) a chelating agent at a concentration no greater than about 10 mM; and

(b) a tonicifier ~~tonicifer~~ at a concentration no greater than about 150 mM.

84. (previously presented) The pharmaceutical composition of claim 83, wherein said tonicifier is selected from the group consisting of NaCl, glycine, sucrose, mannitol, and mixtures thereof.

85. (previously presented) The pharmaceutical composition of claim 82, further comprising one of:

(a) about 0.5% to about 2% w/v glycerol;

(b) about 0.1% to about 1% w/v methionine; and

(c) about 0.1% to about 2% w/v monothiolglycerol.

86. (previously presented) The pharmaceutical composition of claim 82, wherein said polypeptide is present in a concentration range of about 0.05 to about 30 mg/ml (w/v).

87. (previously presented) The pharmaceutical composition of claim 86, wherein said polypeptide is present in a concentration range of about 0.1 to about 20 mg/ml (w/v).

88. (previously presented) The pharmaceutical composition of claim 87, wherein said polypeptide is present in a concentration range of about 0.2 to 4 mg/ml (w/v).

89. (previously presented) The pharmaceutical composition of claim 82, wherein said diluent is water.

90. (previously presented) The pharmaceutical composition of claim 83, wherein said chelating agent is EDTA at a concentration of about 1 mM, and said tonicifier is present at a concentration of about 125 mM.

91. (previously presented) The pharmaceutical composition of claim 82, wherein said pH is from about pH 5.5 to about 6.5.

92. (previously presented) The pharmaceutical composition of claim 91, wherein said pH is about pH 6.0.

93. (previously presented) The pharmaceutical composition of claim 82, wherein said buffer is selected from the group consisting of phosphonic, acetic, aconitic, citric, glutaric, malic, succinic carbonic acid, and an alkali or alkaline earth salt thereof.

94. (previously presented) The pharmaceutical composition of claim 93, wherein said buffer is a phosphate, acetate or citrate salt.

95. (previously presented) The pharmaceutical composition of claim 93, wherein said buffer is a citrate salt.

96. (previously presented) The pharmaceutical composition of claim 82, wherein said buffer is present in a concentration range of about 5 mM to about 30 mM.

97. (previously presented) The pharmaceutical composition of claim 96, wherein said buffer is a citrate salt present in a concentration of from about 10 mM to about 20 mM.

98. (previously presented) The pharmaceutical composition of claim 82, further comprising a stabilizing amount of one or more of (a) an antioxidant or (b) a thiol-compound.

99. (previously presented) The pharmaceutical composition of claim 82, wherein said composition is maintained at a temperature at or below -20°C.

100. (previously presented) The pharmaceutical composition of claim 82, wherein said polypeptide is selected from the group consisting of (i) Ser (69) – Ser (208) of SEQ ID NO:2; (ii) Ser (69) – Ser (208) of SEQ ID NO:2 with a methionine at the N-terminus; and (iii) a mixture of (i) and (ii).

101. (previously presented) The pharmaceutical composition of claim 82, further comprising a bulking agent.

102. (previously presented) The pharmaceutical composition of claim 101, wherein said bulking agent is selected from the group consisting of sucrose, glycine, mannitol, trehalose, and mixtures thereof.

103. (previously presented) The pharmaceutical composition of claim 102, wherein said bulking agent is sucrose or a mixture of sucrose and glycine.

104. (previously presented) The pharmaceutical composition of claim 83, further comprising a bulking agent.

105. (previously presented) The pharmaceutical composition of claim 102, wherein said bulking agent is present in a concentration of about 2% to about 10% w/v.

106. (previously presented) The pharmaceutical composition of claim 102, wherein said bulking agent is 5% mannitol, 7% sucrose, 8% trehalose, or 2% glycine + 0.5% sucrose.

107. (previously presented) The pharmaceutical composition of claim 101, wherein said pH is about pH 6.2.

108. (previously presented) The pharmaceutical composition of claim 101, wherein said diluent is water.

109. (previously presented) The pharmaceutical composition of claim 101, wherein said buffer is selected from the group consisting of phosphonic, acetic, aconitic, citric, gluraric, malic, succinic carbonic acid, and an alkali or alkaline earth salt thereof.

110. (previously presented) The pharmaceutical composition of claim 109, wherein said buffer is a phosphate or citrate salt.

111. (previously presented) The pharmaceutical composition of claim 110, wherein said buffer is a citrate salt.

112. (previously presented) The pharmaceutical composition of claim 108, wherein over 90% of the water is removed by lyophilization.

113. (previously presented) The pharmaceutical composition of claim 112, which is reconstituted in with an amount of sterile water effective to maintain isotonic conditions of 290 mOsm.

114. (previously presented) The pharmaceutical composition of claim 101, wherein said buffer is added in a concentration from about 5 mM to about 50 mM

115. (previously presented) The pharmaceutical composition of claim 114, wherein said buffer is citrate at a concentration of about 10 mM.

116. (previously presented) The pharmaceutical composition of claim 101, further including a stabilizing amount of one or more of (a) an antioxidant, or (b) a thiol-compound.

117. (previously presented) The pharmaceutical composition of claim 112, wherein said composition is reconstituted in sterile water containing a stabilizing amount of an antioxidant comprising: a) about 0.01% to about 2% w/v monothioglycerol, b) about 0.01% to about 2% w/v ascorbic acid, c) about 0.01% to about 2% w/v methionine or d) combinations thereof.

118. (previously presented) The pharmaceutical composition of claim 82, further comprising a thickening agent in an amount effective to raise the viscosity to about 50 to about 10,000 cps.

119. (previously presented) The pharmaceutical composition of claim 118, wherein said thickening agent is present in an amount effective to raise the viscosity to about 50 to about 1,000 cps.

120. (previously presented) The pharmaceutical composition of claim 119, wherein said thickening agent in an amount effective to raise the viscosity to about 200 to about 300 cps.

121. (previously presented) The pharmaceutical composition of claim 82, further comprising a thickening agent is present in a concentration of 0 to 5% (w/w).

122. (previously presented) The pharmaceutical composition of claim 118, wherein said thickening agent is a water soluble etherified cellulose or a carbomer.

123. (previously presented) The pharmaceutical composition of claim 122, wherein said etherified cellulose is an alkyl cellulose, hydroxyalkyl cellulose, carboxyalkyl cellulose or alkylhydroxyalkyl cellulose.

124. (previously presented) The pharmaceutical composition of claim 122, wherein said etherified cellulose is methylcellulose, hydroxyethyl cellulose, hydroxy propyl cellulose, hydroxy propyl methylcellulose, or carboxymethyl cellulose.

125. (previously presented) The pharmaceutical composition of claim 82, further comprising a thickening agent, wherein said thickening agent is a water soluble etherified cellulose derivative selected from the group consisting of methyl cellulose, hydroethyl cellulose, hydroxy propyl cellulose, hydroxy propyl methylcellulose, or carboxymethyl cellulose, wherein said etherified cellulose derivative has a molecular weight of about 50,000 to about 700,000 and is present in a concentration of about 0 to about 20% by weight.

126. (previously presented) The pharmaceutical composition of claim 125, wherein said etherified cellulose derivative has a molecular weight of about 80,000 to about 240,000 and is present in a concentration of about 2% to about 8% by weight.

127. (previously presented) The pharmaceutical composition of claim 120, wherein said buffer is citrate in a concentration of about 10 mM to about 50 mM.

128. (previously presented) The pharmaceutical composition of claim 127, wherein said buffer is citrate in a concentration of about 10 mM to about 20 mM citrate.

129. (previously presented) The pharmaceutical composition of claim 127, wherein said bulking agent is sucrose in a concentration of about 0% to about 5% sucrose.

130. (previously presented) The pharmaceutical composition of claim 129, wherein said thickening agent is added directly to a liquid formulation and thereafter lyophilized.

131. (previously presented) The pharmaceutical composition of claim 129, wherein said thickening agent is added to a lyophilized formulation by reconstituting said formulation by adding a suitable diluent having a thickening agent dissolved therein.

132. (currently amended) The pharmaceutical composition of claim 101, further comprising a thickening agent in an amount effective to raise the viscosity ~~vicosity~~ to about 50 to about 10,000 cps.

133. (previously presented) The composition of claim 82, further comprising a gelling agent in an amount effective to raise the viscosity to about 0 to about 10,000 cps at room temperature.

134. (previously presented) The composition of claim 101, further comprising a gelling agent in an amount effective to raise the viscosity to about 0 to about 10,000 cps at room temperature.

135. (previously presented) The composition of claim 133, wherein said gel forming agent is a water-soluble polymer capable of forming a viscous aqueous solution, or non-water soluble, water-swellable polymer capable of forming a viscous solution.

136. (previously presented) The composition of claim 135, wherein said gel forming agent is a high molecular weight polymer selected from the group consisting of vinyl polymer, polyoxyethylene-polyoxypropylene copolymer, polysaccharide, protein, poly(ethylene oxide), acrylamide polymer or a salt thereof.

137. (previously presented) The composition of claim 136, wherein said gel forming agent is (1) a vinyl polymer selected from the group consisting of polyacrylic acid, polymethacrylic acid, polyvinyl pyrrolidone polyvinyl alcohol, and salts and esters thereof; or (2) a polysaccharide selected from the group consisting of a cellulose derivative, a glycosaminoglycan, agar, pectin, alginic acid, dextran, α-amylose, amylopectin, chitosan, or salts esters thereof.

138. (previously presented) The composition of claim 136, wherein said gel forming agent is a glycosaminoglycan selected from the group consisting of hyaluronic

acid, chondroitin, chondroitin-4-sulfate, heparan sulfate, heparin and salts and esters thereof.

139. (previously presented) The composition of claim 138, wherein said glycosaminoglycan is present in combination with collagen, gelatin, or fibronectin.

140. (previously presented) The composition of claim 136, wherein said gel forming agent is an acrylamide polymer selected from the group consisting of a polyacrylamide or a polymethacrylamide.

141. (previously presented) The composition of claim 136, wherein said gel forming agent is a polyoxyethylene-polyoxypropylene block copolymer.

142. (previously presented) The composition of claim 141, which comprises about 10 to about 60% by weight of a polyoxyethylene-polyoxypropylene block copolymer having an average molecular weight of about 500 to 50,000.

143. (previously presented) The composition of claim 142, which comprises about 14 to about 18% by weight of a polyoxyethylene-polyoxypropylene block copolymer having a molecular weight in the range 1,000 to 15,000.

144. (previously presented) The pharmaceutical composition of claim 82, wherein said polypeptide is present in a concentration range of about 0.01 mg/ml to about 10 mg/ml (w/v).

145. (previously presented) The pharmaceutical composition of claim 82, further comprising one of:

(a) lysine;

(b) hydroxypropyl-β-cyclodextrin; and

(c) sulfated-β-cyclodextrin;

or combinations thereof.

146. (canceled)

147. (currently amended) The pharmaceutical composition of claim ~~146~~ 82, wherein said mixture consists of 0.18% methyl paraben and 0.02% propyl paraben.

148. (previously presented) A pharmaceutical composition produced by the process of admixing:

(a) about 1.0 mg/ml of a polypeptide comprising Ser (69) – Ser (208) of SEQ ID NO:2;

(b) 20 mM citrate, pH 5-5.5; and

(c) 0.01% polysorbate 80.

149. (previously presented) The pharmaceutical composition of claim 148, further comprising 1 mM EDTA.

150. (previously presented) The pharmaceutical composition of claim 148, wherein said polypeptide is selected from the group consisting of: (i) Ser (69) – Ser (208) of SEQ ID NO:2; (ii) Ser (69) – Ser (208) of SEQ ID NO:2 with a methionine at the N-terminus; and (iii) a mixture of (i) and (ii).

151. (previously presented) A pharmaceutical composition produced by the process of admixing:

(a) about 3.3 mg/ml of a polypeptide comprising Ser (69) – Ser (208) of SEQ ID NO:2;

(b) 10 mM sodium citrate;

(c) 20 mM sodium chloride;

(d) 1 mM EDTA;

(e) 2% w/v glycine;

(f) 0.5% w/v sucrose; and

(g) water;

wherein the composition is at a pH or about 6.2.

152. (previously presented) The pharmaceutical composition of claim 151, wherein over 90% of the water is removed by lyophilization.

153. (previously presented) The pharmaceutical composition of claim 151, wherein said polypeptide is selected from the group consisting of: (i) Ser (69) – Ser (208) of SEQ ID NO:2; (ii) Ser (69) – Ser (208) of SEQ ID NO:2 with a methionine at the N-terminus; and (iii) a mixture of (i) and (ii).

154. (previously presented) A pharmaceutical composition produced by the process of admixing:

(a) about 1.0 mg/ml of a polypeptide comprising Ser (69) – Ser (208) of SEQ ID NO:2;

(b) 0.46% hydroxyethylcellulose;

(c) 7% sucrose;

(d) 20 mM sodium citrate;

(e) 20 mM sodium chloride;

(f) 1 mM EDTA;

wherein the composition is at a pH of about 6.2.

155. (previously presented) The pharmaceutical composition of claim 154, wherein said polypeptide is selected from the group consisting of: (i) Ser (69) – Ser (208) of SEQ ID NO:2; (ii) Ser (69) – Ser (208) of SEQ ID NO:2 with a methionine at the N-terminus; and (iii) a mixture of (i) and (ii).